K043293

DEC 17 2004

510(k) Summary

Mini Gamma Camera MGC500-101U and MGC500-301U

Classification Name: Scintillation Camera
21 CFR 892.1100

Acrorad Company, Ltd.
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Contact: Atsushi Kyan, Prepared: November 29, 2004

A. LEGALLY MARKETED PREDICATE DEVICE

The Mini Gamma Camera Models MGC500-101U and MGC500-301U are substantially equivalent to the currently marketed MGC500 (K040587).

B. DEVICE DESCRIPTION

The Mini Gamma Camera MGC500-101U and MGC500-301U , are nuclear medical imagers (commonly known as a scintillation or gamma camera) that are smaller, lighter and more portable than most existing gamma cameras. The MGC500-101U and MGC500-301U are intended for use in nuclear medicine procedures, including intraoperative procedures. To collect such information, it extracorporeally detects and visualizes the gamma ray emitted from an administered radiopharmaceutical. While previous gamma cameras have consisted of a sodium iodide scintillating crystal and photomultiplier tube (PMT),.the design of the MGC500-101U and MGC500-301U incorporate solid-state CdTe semiconductor detectors. This allows the device to be smaller, lighter, and more portable.

Both of the modified models have a new high-uniformity mode and the Model MGC500-301U has been reconfigured into a more compact design.

C. INTENDED USE

The Mini Gamma Camera MGC500-101U and MGC500-301U are indicated for use in imaging the distribution of radionuclides in the human body using planer imaging techniques. The MGC500-101U and MGC500-

301U may also be used intraoperatively if a protective sheath is used.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The MGC-500-101U and MGC500-301U are medical devices, and they have the same indications for use and target population as the legally marketed predicate device. The MGC-500-101U and MGC500-301U have the same technological characteristics as the predicate device. Many of the characteristics of the device are sufficiently precise that performance data are not required, but for others, performance data were collected. The verification/validation activities carried out under Acrorad's procedures for medical device development and modification ensure that the new versions of the device are substantially equivalent[1] to the currently marketed version of the device.

E. TECHNOLOGICAL CHARACTERISTICS

The proposed and predicate devices both use a detector head with CdTe detectors that convert photon energy into electrical signals. The electrical signals generated by the incoming gamma photons are proportional to energy of the photons. Discriminators are used in hardware or software in both proposed and predicate devices to limit acceptable detection events to the gamma energy of the radiopharmaceutical being used for imaging. The location of a gamma detection event is determined by the location of the channel of the detector, and standard image processing algorithms are used to present the image to the user. These technological characteristics are unchanged from the original version of the device.

F. TESTING

The **Mini Gamma Camera MGC500-101U and MGC500-301U** were tested to the specifications of the NEMA Performance Standard for scintillation cameras. It was also tested to the requirements of the IEC-60601-1 for electrical safety.

G. CONCLUSIONS

This pre-market notification has demonstrated Substantial Equivalence as defined and understood in Sections 513(f)(1) and 513(i)(1) of the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

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1 The meaning of the terms "substantial equivalence" and "substantially equivalent" as used in this 510(k) is limited to the way they are defined in, and used by FDA in accordance with, Sections 513(f)(1) and 513(I)(1) of the Federal Food, Drug, and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2004

Acrorad Company, Ltd.
% T. Whit Athey, Ph.D.
Senior Consultant
Health Policy Resources Group, LLC
2305 Gold Mine Road
BROOKVILLE MD 20833

Re: K043293
Trade/Device Name: Mini Gamma Camera
MGC500-101U and MGC500-301U
Regulation Number: 21 CFR 892.1100
Regulation Name: Scintillation (gamma) camera
Regulatory Class: II
Product Code: 90 KPS
Dated: November 29, 2004
Received: November 29, 2004

Dear Dr. Athey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043293

Device Name: Mini Gamma Camera MGC500-101U and MGC500-301U

Indications For Use:

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Prescription Use ___X___ ~~AND~~/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Seyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043293